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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Rajiv Yadav
McCutchen, Doyle, Brown & Emersen, LLP
18th Floor
Three Embarcadero Center
San Francisco, CA 94111

EXAMINER

COOK, LISA V

ART UNIT

PAPER NUMBER

1641

9

DATE MAILED: 05/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/929,293

Applicant(s)

DENNY ET AL.

Examiner

Lisa V. Cook

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2003.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) 32-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-71 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Applicant's election with traverse of Group I (Claims 1-31) in Paper No. 8 filed 2/18/03 is acknowledged. The traversal is on the ground(s) that no serious burden of examination has been established and the groups are not independent and distinct because they all involve the detection of mucin have been carefully considered but not found persuasive.

2. This is not found persuasive because MPEP § 808.02 recites:

Where related inventions as claimed are shown to be distinct under the criteria of MPEP § 806.05(c)- § 806.05(i), the examiner, in order to establish reasons for insisting upon restriction, must show by appropriate explanation one of the following: (A) Separate classification thereof, (B) A separate status in the art when they are classified together, or (C) A different field of search.

3. In the instant case, (A) -The Restriction Requirement under 35 U.S.C. § 121 in Paper #6 established distinctness of the inventions and separate classification thereof.

4. (B) The inventions of Groups I, II, and III would require a separate status in the art when they are classified together; the invention as a whole is drawn to **mucin** detection. Such inventions are classified in 530, subclass 836 for example.

5. (C) With respect to a different field of search – Because these inventions are distinct and have acquired separate status in the art as shown by their different classification, recognized divergent subject matter and because the search required for each invention is not substantially coextensive with the search required for the remaining invention, restriction for examination purposes as indicated is proper.

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6. Further, the combination of Groups I, II and III for examination on the merits is deemed incorrect. The merging of these groups would combine patentably distinct inventions.

Specifically the invention of Group I is directed to a method which merely detects a component in isolated mucin as a measure of predicting a disease. While Group II is drawn to therapeutic administration of a reagent wherein a component of mucin is correlated with oral fluid standard thereby reducing the risk of a disease. The methods have different method steps and utilized diverse reagents. Group I does not require therapeutic administration or oral standards.

The kit/product of invention Group III can be practiced with either of the materially different processes of Group I or Group II. Accordingly restriction is proper.

The Restriction Requirement is still deemed proper and is therefore made **FINAL**.

7. Examiner has reconsidered the restriction of claims 1-31 and found it necessary to provide the following Species Election/Restriction. Examiner apologizes for any inconvenience this may cause Applicant.

Election/Restrictions

8. This application contains claims directed to the following patentably distinct species of the claimed invention: Applicant is required to select one claim from groups A-C and one claim combination (I-V) group D for consideration.

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- A. Saliva Sample – either claim 2 or claim 3 must be selected.
- B. Component – claim 4, claim 5, or claim 6 must be selected.
- C. Mucin – claim 7, claim 8, or claim 9 must be selected.
- D. Disease Assessment – one of the following combinations (I-V) must be selected.
 - I. Periodontal diseases – claims 23, 24, and 26
 - II. Cardiovascular diseases – claims 23 and 25
 - III. Diabetes – claims 23 and 27
 - IV. Mucosal infections – claims 23 and 29
 - V. Dental caries – claims 23, 30, and 31

9. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1 and 10-22 are generic.

10. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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11. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.


12. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 308-4242, which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (703) 305-0808. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Lisa V. Cook
CM1-7B17
5/2/03


LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

05/04/13